



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

20995 7590 03/09/2007
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
----------	--------------

3735

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.		Applicant(s)	
	09/447,227		SHULTS ET AL	
	Examiner		Art Unit	
	Robert L. Nasser		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35, 39, 41, 42, 48, 49, 53-84 and 389 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35, 38, 39, 41, 42, 48, 49, 53-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
- 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 3735

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims, as written recite an outer first domain that supports tissue ingrowth, a second middle domain that is impermeable to macrophages, and a third, inner layer that is a sensing membrane. However, claims 35 and 39 recite that the second or middle domain is an angiogenic layer or promotes vascularization. There is no support for either the angiogenic or vascular promoting layer being beneath the bioprotective layer (impermeable to macrophages) or for the angiogenic or vascularization promoting layer being impermeable to macrophages. Since the features were introduced via amendment, they constitute new matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-35, 38, 39, 41, 42, and 56-83 are rejected under 35 U.S.C. 103(a) as being obvious over Allen et al in view of the Gilligan et al article entitled "Evaluation of a subcutaneous glucose model out to ... and Picha 5706807. Allen et al shows a sensor having a base 17, having a glucose sensor mounted on the base and a membrane over the sensor. The membrane and sensor form a protruding tip the base. The membrane system does not have the structure recited in the claims. Gilligan et al teaches a membrane system that meets the claim language including a Dacron angiogenic layer, a bioprotective layer, and a sensing membrane having an enzyme, in that order, to improve the accuracy of glucose measurement. As such, it would have been obvious to modify Allen to use the membrane structure of Gilligan, so as to improve the accuracy of measurement. The angiogenic layer does not lie on the sensing surface. However, Picha shows a similar device where such an angiogenic layer surrounds the entire sensing area. As such, it would have been obvious to modify the combination to engulf the entire device in the Dacron, as it is merely the substitution of one known configuration for another. Claims 33 and 41 are rejected in that the device is wholly implanted in a host. Claim 42 is further rejected in that Gilligan further teaches telemetering the data to a remote receiver. As such, it would have been obvious to modify the combination to use a wireless telemetry communication system, s it is merely the substitution of one known equivalent transmission means for another. With respect to claims 56-58, it is the examiner's position that given that the device of the combination has the same structure as the claimed invention, it would measure glucose accurate for the time periods. The examiner notes that Gilligan is only concerned with

up to 114 days, but notes that it is the examiner's position that it measures accurately for as long as 360 days. With respect to claims 59-61, applicant has admitted that it is known to explant the device when the useful life of the device is over. Claim 62 and 63 are rejected in that since the angiogenic layer is polyester and therefore made from the same material as applicant's, it would function in the same manner. Claims 64-65 are rejected for the reasons given above. With respect to claims 66-69 the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Allen to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another. Claims 70-72, and 76-78 are rejected for the reasons given above. With respect to claims 73-75, the examiner takes official notice that it is known to explant the device when the useful life of the device is over. With respect to claims 80-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Allen to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 48, 49, and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al in view of Gilligan et al and Picha, as applied to claims 33-35, 38, 39, 41, 42, and 56-83 above, and further in view of Ward et al 5711861. The combination uses an enzymatic membrane, but does not state what the enzyme is. Ward teaches using glucose oxidase as the enzyme. Hence, it would have been obvious to modify the above combination to use glucose oxidase, as it is merely the use of a well known enzyme for the purpose of the combination. With respect to claims 54-

55. Ward further teaches a membrane system with an electrolytic phase. As such, it would have been obvious to modify the combination above to use the membrane system of Ward, as it is merely the substitution of one known membrane system for another.

Applicant's arguments filed 12/4/2006 have been fully considered but they are moot in view of the new grounds of rejection.

Applicant has stated that Allen is not a protruding tip. Applicant has not provided any reasoning in support of this. It appears to the examiner that the membrane protrudes from the housing and forms a tip. Hence, it is a protruding tip.

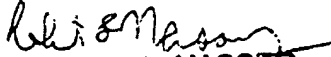
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
March 5, 2007


ROBERT L. NASSER
PRIMARY EXAMINER